

**IN THE UNITED STATES DISTRICT COURT FOR THE
WESTERN DISTRICT OF MISSOURI
CENTRAL DIVISION**

Earl Ringo, Jr., et al.,)	
)	
Plaintiffs,)	
)	
v.)	Case No. 09-4095-CV-C-NKL
)	
George A. Lombardi, et al.,)	
)	
Defendants.)	

ORDER

Plaintiffs seek a declaratory judgment that Missouri’s lethal injection protocol violates the Controlled Substances Act (“CSA”), 21 U.S.C. §§ 801, *et seq.*, as well as the Food, Drug and Cosmetic Act (“FDCA”), 21 U.S.C. §§ 301, *et seq.* Plaintiff Dennis Skillicorn is deceased, having been executed by lethal injection in 2009; the surviving Plaintiffs are prisoners of the State of Missouri sentenced to death. They name the following Defendants: Director of Missouri’s Department of Corrections, George Lombardi; Warden, Eastern Reception Diagnostic & Correctional Center, Steve Larkins; and Anonymous Executioner, John Does 2-40. Plaintiffs assert that Defendants' use of lethal injection drugs (sodium thiopental, pancuronium bromide, and potassium chloride): (1) violates the CSA because Defendants do not obtain the drugs lawfully; and (2) violates the FDCA because the drugs are not prescribed by a licensed practitioner and have not been approved by the FDA for use in lethal injections.

Pending before the Court is Defendants' Motion for Judgment on the Pleadings [Doc. # 98]. For the reasons stated below, the Court denies the motion in part and grants it in part.

I. Background

For purposes of this motion for judgment on the pleadings, the Court assumes true the factual allegations of Plaintiffs' Complaint. Those facts and relevant background are set forth in this Court's Order [Doc. # 72, pp. 2-6] on Defendants' amended motion to dismiss.

A. The Complaint

In the Complaint, Plaintiffs say that their action is "brought pursuant to 28 U.S.C. § 1331 for violations and threatened violations of the" CSA and FDCA. They say that Defendants are required to obey the CSA and FDCA under the Supremacy Clause of the United States Constitution. The Complaint states that this Court has jurisdiction under: § 1331 in that Plaintiffs' claims arise under the Constitution or laws of the United States; the FDCA, specifically 21 U.S.C. § 332; the All Writs Act, 28 U.S.C. § 1651; and the Declaratory Judgment Act, 28 U.S.C. § 2201(a). In the Complaint, Plaintiffs state that they are not seeking to enforce the CSA or FDCA. Instead, Plaintiffs seek a declaration that Defendants' intended actions as applied to Plaintiffs would violate the CSA and FDCA.

II. Discussion

On motions for judgment on the pleadings, the court accepts as true the facts pleaded by the nonmoving party and grants all reasonable inferences from the pleadings in favor of the nonmoving party. *See Syverson v. FirePond, Inc.*, 383 F.3d 745, 749 (8th Cir. 2004) (citation omitted). Rule 12(c) motions are considered under standards governing Rule

12(b)(6) motions. *See Wescott v. City of Omaha*, 901 F.2d 1486, 1488 (8th Cir.1990). “Judgment on the pleadings is appropriate where no material issue of fact remains to be resolved and the movant is entitled to judgment as a matter of law.” *Syverson*, 383 F.3d at 749 (citation omitted). A complaint must plead “enough facts to state a claim to relief that is plausible on its face.” *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570, 127 S. Ct. 1955, 167 L.Ed.2d 929 (2007). “Once a claim has been stated adequately, it may be supported by showing any set of facts consistent with the allegations in the complaint.” *Id.* at 546.

A. Private Rights of Action under the CSA and FDCA

The parties dispute whether the CSA and FDCA allow for private declaratory judgment actions. The Court must consider whether they do and, if not, whether Plaintiffs have otherwise stated a claim. The Court looks first to whether the CSA and FDCA provide private rights of action. The question of whether the FDCA creates a private right of action has already been resolved. The Supreme Court of the United States has confirmed that, via 21 U.S.C. § 337, the “FDCA leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance” *Buckman Co. v. Plaintiff’s Legal Comm.*, 531 U.S. 341, 349 (2001); *see also Fiedler v. Clark*, 714 F.3d 77, 79 (9th Cir. 1983) (finding no jurisdiction over a private party’s declaratory judgment action against farmers arising from alleged FDCA violations where the FDCA does not provide a private right of action). With one exception, the cases cited by Plaintiffs allowing private declaratory judgment actions under the FDCA pre-date *Buckman*; the one case that does not is distinguishable in that it was, unlike this case, brought against the FDA under the

Administrative Procedures Act. *See Medical Ctr. Pharmacy v. Mukasey*, 536 F.3d 383 (5th Cir. 2008). The FDCA does not provide a private right of action. Similarly the Court finds that the CSA provides no private right of action. *See McCallister v. Purdue Pharma L.P.*, 164 F. Supp. 2d 783, 793 (S.D. W. Va. 2001) (stating summarily that a review of the CSA establishes no Congressional intent to create a private right of action).

Consideration of the text of the CSA in its entirety indicates that Congress did not expressly provide a private right of action and did not intend to imply a private right of action. When a statute provides specified remedies, courts must use great caution in expanding its sweep to add unspecified ones. *Alexander v. Sandoval*, 532 U.S. 275, 291 (2001); *Karahalios v. National Fed'n of Fed. Employees*, 489 U.S. 527, 533 (1989). The CSA does provide specified remedies. The CSA gives the Attorney General power to enforce its provisions. It grants the Attorney General authority to promulgate rules and regulations, 21 U.S.C. § 821, and the authority to deny, revoke, or suspend registrations, 21 U.S.C. § 824. The CSA provides criminal penalties and fines for violations. *See* 21 U.S.C. §§ 844 - 865. The CSA allows “any person” aggrieved by final “determinations, findings, and conclusions of the Attorney General” to obtain judicial review, placing original jurisdiction in the United States Courts of Appeals. 21 U.S.C. § 877. The CSA does not specify a private remedy for those aggrieved by violations of the CSA.

"Statutes that focus on the person regulated rather than the individuals protected create no implication of an intent to confer rights on a particular class of persons." *Alexander*, 532 U.S. at 289 (citation and internal punctuation omitted). Statutes which focus on the conduct

of the persons who are doing the regulating – rather than those who are regulated or protected – are even one step further away from creating rights giving rise to private rights of action. *See id.* The CSA focuses on administrative requirements that must be met by those handling drugs, including issues such as drug classifications and schedules, 21 U.S.C. § 811, labeling and packaging, 21 U.S.C. § 825, records and reports, 21 U.S.C. § 826, and registration. 21 U.S.C. § 823. As discussed above, it also focuses on the conduct of the Attorney General. The CSA does not focus on the individuals protected by it.

One section of the CSA does create a sliver of space for an argument that Congress intended to create a private right of action for individuals to enjoin violations of the CSA. At 21 U.S.C. § 882(a), the CSA expressly grants district courts jurisdiction to enjoin violations. Of course, a grant of jurisdiction does not alone imply a private right of action; for example, the FDCA contains a similar provision but does not give rise to private claims. *See* 21 U.S.C. § 332 (FDCA). But, unlike the FDCA, the CSA does not expressly limit enforcement proceedings to those brought in the name of the United States. *See* 21 U.S.C. § 337(a) (FDCA). But, in the same section of the CSA granting jurisdiction, a newly-added subsection – § 882(c) regarding online pharmacies – expressly states that the subsection does not create a private right of action, while saying nothing of the rest of the section. *See* 21 U.S.C. § 882(c)(5) (enacted effective 2008) (“No private right of action is created under this subsection.”). Then, the Court must ask whether Congress, by stating that § 882(c) did not create a private right of action, intended or believed that § 882(a) did?

Section 822(c) is not enough to indicate intent to create a private right of action in the CSA. The CSA is aimed at providing a comprehensive set of requirements for controlled substances. As discussed above, in specifying certain types of remedies and in focusing on its regulator and those regulated, the CSA provides the strong indicia of a statute that does not create a private right of action. Section 822(c)'s specification that it does not create a private right of action for that subsection should not be read expansively to indicate that the rest of the statute – while indicating otherwise – does create such a private right. *See generally United States v. Amaya-Portillo*, 423 F.3d 427, 433 (4th Cir. 2005) (reading criminal provisions of the CSA *in pari materia*).

Unless a congressional intent to imply a private remedy can be gleaned from the text of the statute, its structure, or some other source, “the essential predicate of a private remedy simply does not exist.” *Karahalios*, 489 U.S. at 533. The bottom line is that Congress provided specific means of remedying CSA violations via the Attorney General. There is no indication that anything outside the statute would expand that remedy to encompass a private right of action. Absent a strong indicia of congressional intent to the contrary, the Court must conclude that Congress did not intend to provide an unspecified, implied private right of action in the CSA.

Defendants suggest that the intended effect of the declaration that Plaintiffs seek renders this lawsuit an attempt to pursue a private right of action not allowed under the CSA and FDCA. The Court agrees. *See Durr v. Strickland*, No. 2:10-cv-288, 2010 WL 1610592 (S.D. Ohio April 15, 2010), *aff'd*, 602 F.3d 788 (6th Cir. 2010). The *Durr* district court

determined that, because Plaintiff Durr's suit sought a declaratory judgment that would cease the alleged CSA and FDCA violations, it amounted to a private enforcement action. *See id.* In a brief opinion, the United States Court of Appeals for the Sixth Circuit affirmed, stating: "[W]e agree with [the district court] that this action for declaratory relief is not the proper mechanism for seeking injunctive relief from execution." *Durr*, 602 F.3d at 788. An action based purely on the CSA and FDCA that would require Defendants to come into compliance with the CSA and FDCA, amounts to a private enforcement action not allowed by the statutes. As to Plaintiffs' claim seeking a declaratory judgment that the State is violating the CSA and the FDCA, the Court grants judgment on the pleadings in favor of the Defendants.

B. Preemption

The parties have also raised the issue of preemption in this case. On Defendants' motion to dismiss, the Court ruled that it is too soon to evaluate the extent to which preemption analysis is appropriate.

Here, as Defendants acknowledged in briefing their motion to dismiss, Plaintiffs cite to the Supremacy Clause of the United States Constitution in their Complaint, indicating that they are raising preemption claims. The CSA provides that it does not preempt state law on "the same subject matter which would otherwise be within the authority of the State, unless there is a positive conflict between" the CSA "and State law so that the two cannot consistently stand together." 21 U.S.C. § 903. It does not appear that the FDCA contains a similar provision. But it is well settled that even statutes which do not expressly preempt state law may do so either where compliance with both federal and state law is impossible,

or where the state law is an obstacle to the accomplishment and execution of congressional purposes and objectives. *See Mensing v. Wyeth*, 588 F.3d 602 (8th Cir. 2009); *Lankford v. Sherman*, 451 F.3d 496, 510 (8th Cir. 2006).

Courts have repeatedly entertained federal preemption claims seeking declaratory and injunctive relief even where the statutes at issue do not grant a private right of action. *See Planned Parenthood of Houston & Southeast Tex. v. Sanchez*, 403 F.3d 324, 331-334 (5th Cir. 2005) (discussing fully the various potential bases for jurisdiction over those claims and for implying a private right of action; finding that abortion service providers stated a preemption claim on their Supremacy Clause challenge to a state statute precluding payment of federal funds to organizations providing abortion services). In such cases, a statutory grant of a cause of action is not necessary. *Id.*

Courts have indicated differing bases for finding private rights of action in preemption cases where the statutes at issue do not grant them. One theory notes that, while the Declaratory Judgment Act does not provide an independent basis for federal jurisdiction, *see Skelly Oil Co. v. Phillips Petroleum Co.*, 339 U.S. 667, 671-74 (1950); *Zutz v. Nelson*, 601 F.3d 842, 850 (8th Cir. 2010), it does allow courts to “declare the rights and other legal relations of any interested party seeking [a] declaration, whether or not further relief is or could be sought.” 28 U.S.C. § 2201(a). The Declaratory Judgment Act “might well provide a cause of action where, as here, [preemption] jurisdiction is well-established.” *Planned Parenthood*, 403 F.3d at 334. Another theory is tied to the doctrine of *Ex parte Young*, 209 U.S. 123 (1908), under which state officials may be sued in their official capacities for

prospective declaratory and injunctive relief where plaintiffs allege that the officials are violating federal law. *Id.* at 159-60; *Green v. Mansour*, 474 U.S. 64, 68 (1985); *Dakota, Minn. & E. R.R. Corp. v. South Dakota*, 362 F.3d 512, 516-17 (8th Cir. 2004) (applying *Ex parte Young*, allowing declaratory and injunctive suits against state officials, to allow a preemption suit seeking an injunction against a governor's enforcement of a state statute which was in conflict with federal railroad statutes); *see also* Charles A. Wright, Arthur R. Miller & Edward H. Cooper, *Federal Practice & Procedure: Jurisdiction* § 3566 (3d ed. 2010) ("The best explanation of *Ex parte Young* and its progeny is that the Supremacy Clause creates an implied right of action for injunctive relief against state officers who are threatening to violate the federal Constitution and laws."). Provided the federal statute at issue does not divest federal courts of their authority under 28 U.S.C. § 1331, courts may entertain preemption claims even where the statute does not expressly confer jurisdiction. *See Verizon v. Maryland, Inc. v. Public Serv. Comm'n of Md.*, 535 U.S. 635, 642 (2002) (implying, in review of a preemption claim, that jurisdiction to review the claim created a cause of action). "While there may be some lack of harmony in the case law," the rule is that there is an implied right of action for injunctive and declaratory relief against state or local regulation that is preempted by a federal statutory provision; that such action falls within the federal question jurisdiction of the district courts is well established. *Planned Parenthood*, 403 F.3d at 334 (citation to quotation omitted); *see also Pharm. Research & Mfrs. of America v. Walsh*, 538 U.S. 644, 661-69 (2003) (indicating that a Supremacy Clause preemption claim exists by considering a claim that alleged a conflict between a state statute

and the Medicaid Spending Clause statute; the lower court had observed that the plaintiff was not asserting an action to enforce the Medicaid statute, but was asserting a preemption-based challenge under the Supremacy Clause); *Lankford*, 451 F.3d at 509 (finding that the lack of a federally created “right” required for a 28 U.S.C. § 1983 claim was inconsequential to analysis of a Supremacy Clause preemption challenge to a Missouri statute which allegedly conflicted with the Medicaid statute; “Preemption concerns the federal structure of the Nation rather than the securing of rights, privileges and immunities to individuals.” (quoting *Golden State Transit Corp. v. City of Los Angeles*, 493 U.S. 103, 117 (1989))); *Qwest Corp. v. City of Santa Fe*, 380 F.3d 1258, 1266 (10th Cir. 2004) (“A federal statutory right or right of action is not required where a party seeks to enjoin the enforcement of a regulation on the grounds that the local ordinance is preempted by federal law.”).

Here, citing the Supremacy Clause, Plaintiffs allege that the lethal injection protocol is in conflict with the CSA and FDCA. As discussed above, because preemption claims hinge on the supremacy of federal law, rather than individual rights, the absence of a private right of action in either the CSA or FDCA does not defeat Plaintiffs’ preemption claim. Defendants point to nothing indicating that either statute divests the Court of jurisdiction over such a claim under § 1331. On Defendants’ amended motion to dismiss, the Court rejected Defendants’ argument that the CSA and FDCA should not be considered in this case because they were not intended to address lethal injection situations.

As the Court ruled on Defendants’ motion to dismiss, at this stage of the litigation, it is too soon to proceed with analysis of Plaintiffs’ preemption claims. The parties have not

shared the protocol with the Court, nor discussed its legal impact. As to the protocol, it is not clear that the protocol is even “law” which could be preempted; even if it is law, without knowing the terms of the protocol, the Court cannot determine whether compliance with both federal and state law is impossible such that the protocol is preempted. As to Missouri’s death penalty statute, it requires simply that executions be carried out via “lethal injection” or “lethal gas,” without prescribing any particular method for doing so, *see* Mo. Rev. Stat. § 546.720; on their amended motion to dismiss, Defendants themselves argued that, under Plaintiffs’ allegations, Missouri cannot comply with the CSA and FDCA when performing lethal injections – but the Court cannot make this determination from the face of the pleadings. [*See* Doc. # 38 at 5 (“There is, under [Plaintiffs’] own theory, a direct conflict exists [sic] between state and federal law.”).] Under federal pleading standards, the Complaint states a claim for preemption. Whether the protocol or Missouri’s lethal injection statute can consistently stand together with the CSA and FDCA remains an open question not properly decided on a motion for judgment on the pleadings.

B. Section 1983

The parties discuss another potential basis for Plaintiffs’ claims, 42 U.S.C. § 1983. The *Durr* district court suggested that a suit under § 1983 would be a proper vehicle for considering claims about states failing to extend the protections of the CSA and FDCA to lethal injections. *See Durr*, 2010 WL 1510592, at *4. Though both parties argue the issue, Plaintiffs here have not attempted to state a § 1983 claim, though they say they are “willing” to invoke the statute. Where Plaintiffs have not even attempted to state such a claim, it is not

properly before the Court. *See generally Lankford*, 451 F.3d at 508-09 (noting that “anything short of an unambiguously conferred right does not support an individual right of action under section 1983”) (citation and internal punctuation omitted).

C. Interlocutory Appeal

Pursuant to 28 U.S.C. § 1292(b), Defendants seek an interlocutory appeal of this Order and of the Court’s Order on Defendants’ motion to dismiss. They want a “speedy” resolution of this case, saying its purpose is to delay Plaintiffs’ executions. Defendants state the this lawsuit is forcing them to expend scarce time and resources.

An interlocutory appeal may be taken if the order to be appealed “involves a controlling question of law as to which there is substantial ground for difference of opinion and ... an immediate appeal from the order may materially advance the ultimate termination of the litigation” and the court so certifies. 28 U.S.C. § 1292(b). In order to discourage piecemeal appeals, certification should be “granted sparingly and with discrimination.” *Union County, Iowa v. Piper Jaffray & Co.*, 525 F.3d 643, 646 (8th Cir. 2008) (citation omitted). Certification is appropriate only where appellate resolution would help avoid protracted litigation. *White v. Nix*, 43 F.3d 374, 376 (8th Cir. 1994).

The Court finds that certification is appropriate in this case even though Defendants’ desire to advance this litigation and save money appears to be overstated. Plaintiffs issued their first discovery requests in October 2009, and Defendants moved to stay discovery pending resolution of their motion to dismiss. Defendants chose to file a motion for judgment on the pleadings close to three months after the Court ruled their amended motion

to dismiss; but the issues raised in the motion for judgment could have been more fully addressed in the original motion to dismiss. The parties have agreed to limited discovery, including anonymous depositions taken by telephone. Given the arguments and admissions of the parties to date, it is likely that discovery will reveal no disputed issues of fact, such that resolution at summary judgment is likely, which could be expeditiously completed if the Defendants do not cause further delay. Nonetheless, given the gravity of the interests of both parties, the Court agrees that an interlocutory appeal is appropriate.

D. Conclusion

Accordingly, it is hereby ORDERED that Defendants' Motion for Judgment on the Pleadings [Doc. # 98] is GRANTED IN PART and DENIED IN PART. Plaintiffs fail to state claims arising directly under the CSA and FDCA. Plaintiffs have on the face of their pleadings stated claims for preemption. Defendants' request for interlocutory appeal is GRANTED.

s/ NANETTE K. LAUGHREY
NANETTE K. LAUGHREY
United States District Judge

Dated: August 19, 2010
Jefferson City, Missouri